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| 12/13/99    | FIRST NAMED                | INVENTOR             | T                    | ATTORNEY DOCKET NO. 130-129               |
|-------------|----------------------------|----------------------|----------------------|---|
| 12/13/99    | ASTLE                      |                      | Т                    | 130-129                                   |
|             |                            |                      |                      | 15 'Pen' 'Ph                              |
|             | HM12/0522                  | - <b>-</b> [         |                      | EXAMINER                                  |
| IER         |                            |                      | LU,F                 |   |
| IGTON TURNE | IKE                        | [                    | ART UNIT             | PAPER NUMBER                              |
| 06611       |                            |                      | 1655                 | Z   |
|             |                            |                      | DATE MAILED:         | 05/22/01                                  |
|             | IER<br>GTON TURNP<br>06611 | IER<br>GTON TURNPIKE | IER<br>GTON TURNPIKE | HM12/0522  IER GTON TURNPIKE  06611  1655 |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

## Office Action Summary

Application No. 09/460,107

Applicant(s)

Astle

Examiner

Frank Lu

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|   |  | 1                                   |                     |  |
|---|--|-------------------------------------|---------------------|--|
|   | The MAILING DATE of this communication appear  | s on the cover sh                   | eet with            |  |
|   | for Reply  |                                     |                     |  |
| THE                                     | ORTENED STATUTORY PERIOD FOR REPLY IS SE<br>MAILING DATE OF THIS COMMUNICATION.  |                                     |                     | _  |
| af                                      | nsions of time may be available under the provisions of 37 (<br>ter SIX (6) MONTHS from the mailing date of this communi<br>a period for reply specified above is less than thirty (30) day  | ication.                            |                     |  |
| be<br>- If NC<br>co<br>- Failu<br>- Any | e considered timely.  Define period for reply is specified above, the maximum statutory ommunication.  The to reply within the set or extended period for reply will, be reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b). | period will apply a                 | ind will e          | xpire SIX (6) MONTHS from the mailing date of thi      |
| Status                                  | ,  |                                     |                     |  |
| 1) 💢                                    | Responsive to communication(s) filed on Mar 12,  | 2001                                |                     |  |
| 2a) 🗌                                   | This action is <b>FINAL</b> . 2b) 🔀 This ac  | ction is non-final.                 |                     |  |
| 3) 🗆                                    | Since this application is in condition for allowance closed in accordance with the practice under ${\it Ex\ p}$  | except for form<br>arte Quayle, 193 | al matte<br>35 C.D. | ers, prosecution as to the merits is 11; 453 O.G. 213. |
| Disposi                                 | tion of Claims   |                                     |                     |  |
| 4) 💢                                    | Claim(s) <u>1-28</u>   |                                     |                     | is/are pending in the application.                     |
| 4                                       | a) Of the above, claim(s) 1-11   |                                     |                     | is/are withdrawn from consideration.                   |
| 5) 🗌                                    | Claim(s)   |                                     |                     | is/are allowed.  |
| 6) 💢                                    | Claim(s) 12-23 and 27  |                                     |                     | is/are rejected.                                       |
| 7) 💢                                    | Claim(s) 24-26 and 28  |                                     | <u></u>             | is/are objected to.                                    |
| 8) 🗌                                    | Claims   | are                                 | subject             | to restriction and/or election requirement.            |
| Applica                                 | tion Papers  |                                     |                     |  |
| 9) 🗶                                    | The specification is objected to by the Examiner.  |                                     |                     |  |
| 10)                                     | The drawing(s) filed on is/ard   | e objected to by                    | the Exa             | aminer.  |
| 11)                                     | The proposed drawing correction filed on   | is:                                 | a) 🗌 a              | pproved b) disapproved.                                |
| 12)💢                                    | The oath or declaration is objected to by the Exam   | niner.                              |                     |  |
| Priority                                | under 35 U.S.C. § 119  |                                     |                     |  |
| 13)                                     | Acknowledgement is made of a claim for foreign p   | oriority under 35                   | U.S.C.              | § 119(a)-(d).  |
| a) [                                    | All b) $\square$ Some* c) $\square$ None of:   |                                     |                     |  |
|   | 1. $\square$ Certified copies of the priority documents have   | ve been received                    | ı.                  |  |
| •                                       | 2. $\square$ Certified copies of the priority documents hav  | ve been received                    | in App              | lication No  |
|   | 3. Copies of the certified copies of the priority of application from the International Bure the attached detailed Office action for a list of the   | eau (PCT Rule 17                    | 7.2(a)).            | -  |
| 14) 🗆                                   | Acknowledgement is made of a claim for domestic  |                                     |                     |  |
| N++==                                   |  | , , , ==                            |                     |  |
| Attachme<br>15) 🔽 No                    | ent(s) stice of References Cited (PTO-892)   | 18) Interview Sun                   | omon: (DT)          | 0.412) Paras Nata                                      |
|   | tice of Draftsperson's Patent Drawing Review (PTO-948)   |                                     |                     | 0-413) Paper No(s)<br>t Application (PTO-152)          |
|   | ormation Disclosure Statement(s) (PTO-1449) Paper No(s).   | 20) Other:                          |                     | C - ADDINGULATE OF LAST                                |
|   |  |                                     |                     |  |

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#### **DETAILED ACTION**

#### Response to Appeal Brief

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and reasonable, therefore, the finality of that action is withdrawn.

#### **Priority**

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

#### Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because applicant has not declared the priority of earlier applications which were shown in the specification (page 2).

#### Specification

5. The disclosure remains objected to because of the following informalities: Both Application Serial Nos. 09/271,050 and 09/198,018 are pending application. No patent has

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issued for these cases. The applicant is advised to delete US Patent No. and issued date on line 4, 5, and 8 of page 2 of subject application. Please check the specification for mistakes.

Appropriate correction is required.

### Response to Arguments

The argument "the missing information is still not available, but will be inserted when it does become available" have been fully considered and have not been found pervasive since no patent has issued for the cases 09/271,050 or 09/198,018. The applicant is advised to delete US Patent No. and issued date on line 4, 5, and 8 of page 2 of subject application.

#### Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 12-15, 17-23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Danssaert *et al.*, (US Patent No. 5,779,981, published on July 14, 1998).

Danssaert *et al.*, teach thermal cycler including a temperature gradient block. As shown in Figure 3, in PCR, the first, second, and third blocks were programmed to be maintained at a temperature range of between about 25 °C to 99 °C, and were used for denaturing, annealing and extension respectively. The fourth block (made by metal, see column 5, first paragraph) was generally maintained at between 4 and 25 °C (see column 6, last paragraph). The reaction

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mixtures could be moved between gradient blocks (see column 3, eight paragraph) using RoboCycler system (see Staratagene catalog, pages 256 and 257, 1994) and reactions were carried out in  $500\mu$ l eppendof tubes (see column 7). Note that: (1) the block with a plurality of reaction wells could be considered as index patterns of reagent wells as described in claim 12; (2) different gradient blocks with different temperature could be considered as heat transfer stations as described in claim 12; and (3) a reagent well and  $500\mu$ l eppend tube inside of the reagent well could be considered as a sealed reagent well as described in claim 13 with the limitations of claims 14-17, and 19; (4) the addition of PCR reagents from different stock solutions into the eppendof tubes after the eppendof tubes were inserted into the wells of a metal block could be considered to have the limitations of claims 13, 21, and 22 and stock solutions could be refilled as described in claim 23; (5) RoboCycler system (see above ) could be considered as electronic stepper drive as described in claim 18; and (6) the cap of eppendof tubes could be considered to be peelable as described in claim 27.

Therefore, Danssaert et al., teach all limitations recited by claims 12-15, 17-23, and 27.

Claims 12-17, 19, 21-23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated 5. by Mitsuhashi et al., (US Patent No. 5,545,528, published on August 13, 1996).

Mitsuhashi et al., teach PCR. In experiment 3, single stranded cDNA was mixed with each of the sense and antisense primers, PCR buffer and Taq polymerase (Promega) in each well of a 96 well microtiter plate. PCR was carried out either polypropylene tubes, or polypropylene plates (Coster, Nunc). For tubes, PCR was carried out in thermal cycles (model 480.

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Perkin-Elmer Cetus, Norwalk, Conn.). For Nunc plates, PCR was done in thermal cycles (CMJ Research). For Coster plates, PCR was performed by manually soaking into 3-8 different water bathes (see column 12). Note that: (1) 96 well in the microtiter plate could be considered as index patterns of reagent wells with the limitations of claims 12, 14-17, and 19; (2) different water bathes with different temperature could be considered as heat transfer stations as described in claim 12; (3) the mixing of PCR reagents by pipetting different reagents from their stock solutions can be considered to have the limitations of claims 13, 21 and 22 and stock solutions cold be refilled as described in claim 23; and (4) the cover of microtiter plate could be considered as a peelable sealer of the reagent wells as described in claim 27.

Therefore, Mitsuhashi *et al.*, teach all limitations recited by claims 12-17, 19, 21-23, and 27.

#### Conclusion

- 6. Claims 24-26 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 7. No Claim is allowed.
- 8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94

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(December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu May 21, 2001

Ethan Whisenant, Ph.D. Primary Examiner (FSA)